European Food Safety Authority; Outcome of the Public consultation on the Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition, and Allergies (NDA) on principles for deriving and applying Dietary Reference Values

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SCIENTIFIC REPORT OF EFSA

Outcome of the Public consultation on the Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition, and Allergies (NDA) on principles for deriving and applying Dietary Reference Values[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

On 11 April 2008, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) endorsed a draft Opinion on principles for deriving and applying Dietary Reference Values to be released for public consultation. This Scientific Report summarises the comments received through the public consultation and outlines how these were taken into account in the final opinion.

EFSA had received 38 contributions from 12 interested parties (individuals, non-governmental organisations, industry organisations, academia and national assessment bodies). After a meeting with national experts on Dietary Reference Values which was held in September 2009, 13 additional comments on the draft Opinion on principles for deriving and applying Dietary Reference Values were received from seven Member States.

The main comments which were received during the public consultation related to: the need for a better clarity and consistency in the use of terminology throughout the opinion, the definition and use of Dietary Reference Values, the definition and use of the Tolerable Upper Intake Levels, the age groups used, as well as other and editorial comments.

All the public comments received and comments from Member States that related to the remit of EFSA were assessed and the Opinion on principles for deriving and applying Dietary Reference Values has been revised taking relevant comments into consideration.

1 On request from EFSA, Question No EFSA-Q-2009-00920, issued on 01 March 2010.

2 Correspondence: NDA@efsa.europa.eu

3 Acknowledgement: EFSA wishes to thank the members of the Working Group on Population Reference Intakes for the preparation of this EFSA scientific output: Carlo Agostoni, Jean-Louis Bresson, Jean-Michel Chardigny, Susan Fairweather-Tait, Albert Flynn, Ambroise Martin, Monika Neuhäuser-Berthold, Hildegard Przyrembel, John Joseph Strain, Inge Tetens, Daniel Tomé and EFSA's staff member Silvia Valtueña Martínez for the support provided to this EFSA scientific output.

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BACKGROUND

On 11 April 2008, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) endorsed a draft Opinion on principles for deriving and applying Dietary Reference Values to be released for public consultation.

The scientific advice on nutrient intakes is important as the basis of Community action in the field of nutrition; for example such advice has in the past been used as the basis of nutrition labelling. The Scientific Committee for Food (SCF) report on nutrient and energy intakes for the European Community dates from 1993.

The European Commission has asked EFSA to review and if necessary update such advice to ensure that the Community action in the area of nutrition is underpinned by the latest scientific advice. To this end the EFSA has been requested to consider the existing Population Reference Intakes for nutrients and certain other dietary components.

Furthermore, and in order to communicate effectively on nutrition and on healthy diets to the public at large, it is generally more appropriate to express recommendations for the intake of individual nutrients or substances in food-based terms. To this end EFSA has also been asked by the European Commission to provide assistance on the translation of nutrient based dietary recommendations for a healthy diet into food-based recommendations intended for the European population as a whole.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders on its work, EFSA engages in public consultations on key issues. The work on Dietary Reference Values (DRVs) including food-based dietary guidelines is considered to be such an issue. Accordingly, the draft Opinion on principles for deriving and applying Dietary Reference Values was released for public consultation for four months (from 8 August until 15 December 2008) on the EFSA website[4]. Stakeholders were informed and invited to submit comments.

Together with other draft Opinions on DRVs, the draft Opinion on principles for deriving and applying Dietary Reference Values was also discussed on a National Expert Meeting with Member States on Dietary Reference Values held in Barcelona on 7 and 8 September 2009, with a deadline for written comments by 30 September 2009.

EFSA has committed to publish the comments received during the public consultation as well as a short report on the outcome of the consultation, taking also into account comments received by Member States in the commenting period after the National Expert Meeting.

COMMENTS RECEIVED

At the end of the public consultation period in December 2008 EFSA had received 38 contributions from twelve interested parties (individuals, non-governmental organisations, industry organisations, academia and national assessment bodies). After the National Expert Meeting on Dietary Reference Values in September 2009, 13 additional comments on the draft Opinion on principles for deriving and applying Dietary Reference Values were received from seven Member States. All comments received were scrutinised by the NDA secretariat and subsequently compiled with reference to the contributor and the section of the draft Opinion to which the comment referred (see Appendix). Comments submitted formally on behalf of an organisation appear with the name of the organisation. . The comments received by Member States during the National Expert Meeting are published in the minutes of that meeting on the EFSA website.

[4] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902045161.htm

SCREENING AND EVALUATION OF COMMENTS RECEIVED

1. General comments

In general the comments were constructive and aimed to help improving the draft Opinion. It was noted that several contributions reiterated arguments brought forward already by other organisations.

The majority of the comments supported the general view of the Opinion in the various sections. Some comments congratulated EFSA for the good quality of the document.

Several separate and complementary comments emphasised the need for a better clarity and consistency in the use of terminology throughout the Opinion. In addition, a justification was requested for keeping the terminology proposed by the SCF in 1993 in view of the most recent international discussions on these issues. More specifically, a comment suggests the use of the new terminology proposed by the WHO/UNU expert group in 2007. A comment suggests to clearly distinguish reference values based on scientific assessment from recommendations which may take into account other factors such as dietary habits and actual food composition in a given region or country. This proposal considers that the separation (at least functionally if not institutionally) between assessment and management, like in the other areas of food safety, would be a valuable improvement towards better clarification.

2. Specific comments

The main issues raised in the comments received are summarised by topic below.

Definition and use of the DRVs: A proposal has been made to consider the possibility of deriving reference values in a similar way as that used for deriving the Tolerable Upper intake Level (UL), by establishing a LL (Tolerable Lower intake Level) and applying an uncertainty factor. In addition, several comments argue for the use or Population Reference Intake (PRI) rather than Average Requirement (AR) in nutrition labelling.

Definition and use of the UL: Some comments addressed the setting and the use of the UL and made proposals in the case where an UL cannot be established, by considering the Highest Observed Intake level (HOI) or the Observed Safe Level (OSL).

Usefulness of Lower Threshold of Intake (LTI): Several comments questioned the pertinence and usefulness of establishing the LTI.

Comments on age groups: Several comments emphasised that the use of age groups different from those used by other expert Committees, especially by the US Institute of Medicine, is not clearly justified and introduces difficulties for comparing DRVs at the international level.

Other comments including editorial comments: Some comments suggest introducing specific considerations for certain nutrients, for example for polyunsaturated fatty acids, sugars or fibres. Comments suggested putting more emphasis on some issues, such as the genetic variability, the assessment of study quality, or the probabilistic method for assessing the risk of nutrient inadequacy. There were criticisms on the use of some terms, such as metabolic integrity or balance. Finally, several comments were on editorial errors or requested clarification of some words or formulations.

INCORPORATION OF THE COMMENTS IN THE OPINION

The EFSA NDA Working Group on Population Reference Intakes (PRI) was presented with the compilation of comments and discussed them at a dedicated meeting. Many of the comments were

appropriate and aimed to enhance the scientific quality and clarity of the document. These comments were taken into account and the document was revised accordingly as follows:

Comments on concepts and terminology: These comments were considered as the most important by the Panel, which also considers that changing terminology without changing the basic concepts behind can add to the confusion rather than lead to a better clarification. The Panel has taken into consideration the comments received from the public consultation on the draft Opinions on fats and carbohydrates. In these Opinions, the Panel noted that there was insufficient scientific data to propose values for limiting saturated fat intakes or to derive an UL for sugars or added sugars and concluded that "typically, these recommendations reflect a judgement of what level of SFA intake is practically achievable within the context of a nutritionally adequate diet based on known patterns of intake of foods and nutrients in specific populations." Many comments argued on the need to establish specific guidance values for these nutrients.

In the revised version of the Opinion, the Panel has introduced a new section in the process depicted in section 2 on establishing nutrient goals and recommendations in order to better distinguish between scientific risk assessment and risk management. The former is based only on health and nutrition criteria and it is used to establish Dietary Reference Values for nutrients, whereas the latter can and should take into account other explicit considerations, such dietary habits, actual food composition, realistic goals for a given population, anticipated consequences of some management choices, etc, and it is used together with Dietary Reference Values for nutrients to establish nutrient goals (for populations) and recommendations (for individuals). Terminology and wordings have been adapted accordingly throughout the Opinion.

2.1. Estimating the physiological requirement and metabolic demand

2.2. Establishing the dietary requirement of nutrients

2.3. Establishing Dietary Reference Values

2.4. Establishing nutrient goals and recommendations

2.5. Establishing food based dietary guidelines

In addition, the Panel decided to limit its work to the establishment of Dietary Reference Values for nutrients and other certain dietary components, such as dietary fibre. Consistent with terminology and concepts discussed above, the term "Recommended Intake Ranges" for macronutrients has been replaced with "Reference Intake Ranges" for macronutrients.

Definition and use of DRVs: The Panel considered this comment to be inappropriate. No changes were introduced in the text.

Definition and use of the UL: These comments refer to risk management, i.e. policy and regulatory decisions related to the application of the UL, and are out of the remit of the Panel. Application of the UL is shortly discussed in section 6 (i.e. 6.3.1 and 6.2.1). As indicated in a footnote, the UL concept has already been discussed and agreed in an SCF opinion of February 2000, and UL for micronutrients have already been established by the SCF and EFSA. No change in the text is considered necessary.

Usefulness of LTI: The LTI just marks the lower end of the distribution curve of requirements and, together with AR and PRI, allows a complete description of the requirement distributions. There is indeed no real application at the population level, but is useful for individuals. No change in the text is considered necessary.

Comments on age groups: Though it would be useful to have a worldwide harmonisation of the age ranges for comparisons, the Panel considers that actual choices of age ranges remain somewhat arbitrary in the absence of convincing physiological arguments for defining specific cut-offs. Also, different age ranges may be appropriate for different nutrients depending on the data available, and the choice may also depend on the availability of more recent and representative database of reference weights and heights in the EU. Therefore, the Panel proposes to define the age ranges used for each nutrient on a case-by-case basis depending on the available data and the Opinion has been updated accordingly.

Other comments and editorial comments: Concerning the comments on specific nutrients or foods (fatty acids, carbohydrate and their food vectors), it is not in the scope of this Opinion to discuss specific nutrients or foods. DRVs for specific nutrients (e.g. for fats and fatty acids) are being derived in *ad-hoc* opinions for each nutrient. The translation of DRVs into food-based dietary guidelines (FBDG) for consumers is shortly discussed in section 2.5 on the conceptual framework, i.e. the importance of selection of a suitable mix of foods and of food patterns, and is the subject of a separate Opinion on how to derive and apply FBDG. No change in the text is considered necessary.

Genetic variability has been mentioned as one of the sources of variability, taken into account at the population level by the use of variation coefficients. It was not the scope of this Opinion to discuss in depth all the factors, which will be described as appropriate in the specific Opinions, depending on data availability.

"Metabolic integrity" is a term used to describe the various aspects and complexities involved in maintaining functional competence of cells/tissues and it is explained in section 5.1. To indicate that this is not a true scientific term, 'metabolic integrity' has been cited between quotation marks.

Nutritional Balance: Nutritional balance is a common expression to indicate a daily food intake pattern that allows an adequate intake of all essential nutrients without the risk of an inadequate or excessive energy intake. Interaction between nutrients was not intended in this concept. No change in the text is considered necessary.

Probabilistic methods: In section 6.1.1 probabilistic methods are mentioned as an alternative for the AR cut-point method. The Panel modified the summary of the Opinion accordingly.

All editorial comments were considered and changes introduced in the revised text.

EFSA wishes to thank all stakeholders for their contribution.

GLOSSARY AND ABBREVIATIONS

AR	Average Requirement
DRV	Dietary Reference Value
EFSA	European Food Safety Authority
FBDG	Food-based dietary guidelines
HOI	Highest Observed Intake level
LL	Tolerable Lower intake Level
LTI	Lower Threshold of Intake
OSL	Observed Safe Level
PRI	Population Reference Intake
SCF	Scientific Committee on Food
UL	Tolerable Upper Intake Level
UNU	United Nations University
WHO	World Health Organization

APPENDIX

COMMENTS RECEIVED ON THE DRAFT OPINION RELATED TO DIETARY REFERENCE VALUES FOR CARBOHYDTRATES AND DIETARY FIBRE DURING THE PUBLIC CONSULTATION PERIOD

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Afssa	1. Introduction	1. Line 199 - The French Committee also recognizes the magnitude of the task involved in the request from the Commission. It also strongly supports the development of harmonized European Dietary Reference Values in order to avoid duplication of efforts for such a huge task in each Member States, that leads to a waste of time and human and material resources for similar works. Considering the past history of Dietary reference values, where the publication of the 1993 SCF report has not prevented many countries (including France) to develop their own sets of reference values and recommendations, the Committee would strongly support the implementation of a true European collective expert process, involving experts from national institutions in charge of these reference in the various member states, under the coordination of Efsa. The public consultation launched by Efsa is a valuable first step in this direction, but this should be strengthened e.g. during the step of the management of comments to be sure that the possibly different scientific arguments developed in Member States are discussed in depth and the resulting DRV are agreed by all the involved countries. As an example, Afssa has put in place several working groups, including many experts for up to two years, who have produced important reports (proteins, trans fatty acids, lipids,…) sometimes displaying divergent scientific positions as compared to already known analyses (such as for proteins in the elderly). Possibly, the same has been achieved in some other European countries. Gathering and taking into account all these efforts would lead to a significant improvement of the European opinions and of its influence on this very fundamental and sensitive issues, by developing synergies and collaboration between member states and European institutions.
Afssa	2. General principles for deriving dietary reference values	part 1: Line 221 - As it will become evident from some of the following comments, and it is already evident from the report of the WHO Expert Committee (King and Garza, 2007), divergent views on the interpretation and use of dietary reference values exist. The French suggestion to manage this issue would be to clearly delineate, as in other areas of food safety, what is relevant for assessment and what is relevant for management. The consequence would be to clarify the terminology and to clearly distinguish - Dietary Reference Values, that are true scientific references, and can be considered for the whole european population; the Terms of Reference from the European Commission appropriately use the wording “population reference intakes” and not the terms nutrient recommendations. In this way, Afssa supports the deletion of all the terminologies referring to recommendations in the opinion (unless actually appropriate, see below). - Nutrient recommendations that deal with nutrition policy management, that could be different in the various countries, depending on socio-cultural, geographical, health and dietary context, etc… They should be established by national scientific expert taking into account specific national conditions (see also comment 7). What is true for the

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
		Food based dietary guidelines (as expressed in the corresponding draft opinion) could be also true for what should (could) be called Nutrient based dietary guidelines. Several examples of these differences can be given: - vitamin D: perhaps the reference values will be based on the serum concentration of 25(OH)D3 and should be the same at the European level; depending on the country (sunlight exposure and geography, dietary habits, fortification policies,…), the recommendations for the dietary supply of vitamin D could be different; the choice of a recommended value may be also influenced by the specific levels on calcium intakes in a particular country. - folic acid: the reference could be again the same, but the recommendations could vary, depending for example, of the prevalence of the mutation of the MTHF gene leading to an increase in the recommended level of intake. - for iron, the same could be true, depending on the prevalence of hemochromatosis; - for iodine or selenium, to reach the healthy reference values, recommendations could vary according to the geological characteristics of the country…. In addition: -the choice of an AI (see comment #14) could be also based on specific national conditions; -the choice of the upper bound for some RI (e.g. saturated fat, added sugars, trans fatty acids…) could also be based on national specific considerations (such as feasibility….) when scientific considerations are insufficient to propose a very precise value (for example, it is difficult to scientifically choose between 8 or 10 % for saturated fat or between 1 or 2 % for trans fatty acids). The French Committee considers that is a management choice to actively communicate to consumers two different sets of recommendations: nutrient-based and food-based recommendations. Lines 231-232. It should be important to distinguish between different types of environmental stress: behavioural and social stressors are different from trauma and infection, which are only some examples of pathological conditions that can lead to a modification of nutrient requirements. In this way, it would be important to stress that dietary reference values are addressed to healthy populations (or individuals) and cannot be applied without caution to pathological conditions.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Afssa	2. General principles for deriving dietary reference values	Part 2: Lines 238-239. The metabolic adaptations are likely already taken into account through the statistical techniques that are used in the process of deriving values. To take into account metabolic adaptations would be probably more important for the management of individuals. The sentence could be completed by words like "or managing dietary assessment or planning for individuals". It would be very important for nutrition practitioners that the bases of these adaptations would be clearly indicated in the future opinions on individual nutrients. Line 255. The wording of the title is a good example of the permanent confusion and shift from reference to recommendations (or from assessment to management). The Committee would suggest to replace for this title by "Establishing dietary reference values for nutrient intakes", which would be also more in accordance with the line 263 where the wording "dietary reference values" is appropriately used. See also Comment #7, 8, 9… Lines 263-264 – These two lines are indeed rather a conclusion of this section 2.3 and should be placed at the end. Lines 265-269 – The wordings "recommendations, recommended" will be discussed later in the terminology section (see section 3). According to these comments, the Committee would suggest to add a new distinct paragraph to move from "2.3. Establishing dietary reference values" to "2.4. Establishing Nutrient based recommendations". In this new section, the bases for adapting European references to country specific nutrient recommendations, if this management choice is made, could be: the specific nutrition/nutrient health issues in the country, the specific characteristics of the dietary habits and food supply (that can lead to different nutrient interactions and thus availability), the issues related to the prevalence of specific mutations increasing or decreasing nutrient requirements, the actual intakes of other related nutrients, the feasibility of the recommended value, etc… line 271. The Committee fully agrees with the sentence that "FBDG represent the form in which advice is provided to people to assist them…". It is one of the reasons why the use of the wordings "recommended" or "recommendations" should not be used, since it creates confusion about to whom these recommendations are given. Line 268 (and also line 362) – This wording is rather ambiguous. Indeed, it does not appear (from the text in line 365) that the reference values for energy are derived on a different basis: it is for management reasons that the choice has been made to use the Average Requirement rather than the PRI in setting the recommendation for energy.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Afssa	3. Terminology and definitions	part 1: Lines 281-286. The Committee agrees with the citation of the WHO expert group, but is surprised by the fact that, despite this important publication, no justification is given to keep the earlier terminology proposed by SCF, since the proposals of the WHO group are not neutral and have strong implications that deserve discussion. In addition, since the Committee is aware that the Eurreca network has adopted the WHO terminology, it would be valuable that Europe has a strongly argued scientific position on these important topics and that a common European terminology is adopted, to avoid increasing confusion among European nutritionists. The adoption of (some) of the terminologies proposed by the WHO group could be an important step towards global harmonisation. The clear distinction between references (assessment) and recommendations (management) could form the basis on which it would be possible to reconcile divergent positions on interpretation and use. In France, the choice has been made to have a terminology which is user-oriented, i.e. to use the same wording (ANC, apports nutritionnels conseillés) for the different concepts (PRI, RI, AI) that are in practice used in a similar way by most of the users… However, the Committee agrees with the use of a more accurate terminology in the definition of reference values. The Committee recognizes the difficulty to eliminate the possible confusion of the letter "R" (reference of recommendation) in the choice of an adequate terminology. The change in the wording to eliminate this confusion is one of the bases of the WHO Expert group. Line 287 – The Committee agrees with the terminology DRV but, according to the previous and following comments, would suggest to rephrase the sentence to: "the complete set of reference values that are defined below". Lines 289-290. The Committee agrees with the wording PRI and its definition, but regrets that there is no justification to keep this concept since the WHO group proposed to use instead the concept of INLx (individual nutrient level) with x indicating the percentage of people whose requirements are satisfied, so that PRI = INL97.5. Clearly, the reference (for the same value) to a population in one concept and to an individual in the other is a central issue that would deserve discussions! The Committee thinks that the concept of INLx and the choice of the x value is a management concept based on the assumption that everyone should be at this value to be sure not to be at risk of inadequacy. For the reasons which will be developed later, the Committee has the opinion that the value of 97.5 is not scientifically justified and prefers the reference to a population. The word "population" has the advantage to remind that the values have been derived from data obtained on population or groups and is well applied in the assessment of the distribution of intakes in a population, as indicated later in the opinion. In addition, since emphasis is put later on the importance of examining distribution of intakes rather a single value, it is useful to have the three characteristics of a reference distribution, the tails (with the AR and the UL) and the centre (with the PRI).

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Afssa	3. Terminology and definitions	part 2: Line 291. The Committee agrees with the AR, but could also agree with the terminology ANR (average nutrient requirement) proposed by WHO, since the concepts appear to be the same. However, it would favour the interpretation of the N as "Nutritional" rather than as "nutrient", since the word "nutritional" reflects the fact that ANR takes into account the bioavailability of the nutrient in the diet. Line 299 – For the reasons already expressed, the Committee would prefer the wording "reference intake ranges for macronutrient". Line 301. The Committee agrees with the UL, but could also agree with the terminology UNL proposed by WHO, since the concepts appear to be the same. The WHO Committee has suggested to abandon the notion of AI, due to the lack of scientific justification (it can also be considered as a circular validation to use an observed value as a reference value). To keep this value should also be justified and this can be done for example for management reasons. The choice of the (apparently) healthy population or group on which to base the AI at the European level could also be a matter of discussion.
Afssa	4. Conceptual basis for derivation of dietary reference values	Line 364. The wording "estimated average requirement" (though with no upper case letter) could create confusion with the US Estimated Average Requirement. It is suggested to delete the word "estimated" (indeed, all the AR can be considered as estimated like in the US terminology!).
Afssa	5. Methods for determining dietary reference values - types of data used	Line 396-397. Another limitation of experimental studies in humans is the fact that they cannot take into account subtle long term health effects (beneficial or detrimental). Line 480. The reference to the section 4.1 to 4.3 should perhaps be read as 5.1 to 5.3? Lines 519-520. Updating reference weights and heights representative for the total European population should take into account (and discuss as appropriate) the issue of the increasing prevalence of overweight and obesity throughout Europe…. (since in table 2, the reference is for observed median values). To eliminate this difficulty, the Committee suggests the use of reference growth standards provided by WHO rather than the use of observed values.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Afssa	6. Application of dietary reference values for nutrients	Part 2: Line 618. The sentence "The requirement for there to be low risk of inadequate intake" is not clear. The Committee wonders if it is a result of a wrong "cut-paste"? Lines 619-620. As it is indicated later for individuals, the maintenance of a normal average (or distribution of) weight within a population could also be used as an indication of adequate intakes at the population level. Indeed, the increase in the prevalence of overweight is generally interpreted as a current excessive energy intake at the population level as compared to the requirements. Line 626. The Committee suggests to indicate first anthropometric information, that is readily available, and then the possible use of other clinical and biochemical (that is less frequent in current practice) data. Lines 633-635, in relation also to lines 676-677. The analysis of this point could also be considered as very important. If one agrees with the fact that AR is the best estimate of the prevalence of the risk of inadequacy, it follows that if no people are below this point, the prevalence of the risk of inadequacy is equal to zero for the population. It is the task of the nutritionist or the physician to assess (as indicated in lines 626-627) for a given individual having intakes at the AR value if there is an actual risk of inadequacy. The Committee thinks that, for counselling at the population level, it is advisable that everybody should be at least at the value of AR. In practice, this leads to the fact that a significant proportion of people is at or above the PRI. Whatever the way of dietary planning, the experience (and published papers, such as the book on dietary planning published by IoM) indicates that it is very difficult to design diets that are exactly at the PRI for all the nutrients. From works conducted during the revision of the French ANC, it appears that some nutrients are limiting (especially zinc and iron): if PRI are covered for these limiting nutrients, many other nutrients are largely above the PRI (up to 10 times dependent on the constraints of the models and without the need of fortified products), which appears contradictory with the affirmations that there is no additional benefit but possibly increasing risk to go far beyond the PRI… Section 6.3. The Committee suggests that this section should be revised in the light of the recent publication of the nutrition directive 2008/100/CE of October 28, 2008. This directive proposes labelling reference values, theoretically based on the SCF 2003 report though not all the proposals of this report have been implemented. As expressed in the report on nutrition labelling published by Afssa, the Committee preferentially supports the use of the average requirements though also recognizing that it is rather a management decision.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
British Nutrition Foundation	Conclusions	Dear Sir, The British Nutrition Foundation (BNF) is a not-for-profit organisation with charitable status that promotes the wellbeing of society through the impartial interpretation and effective dissemination of scientifically based knowledge and advice on the relationship between diet, physical activity and health. It works in partnership with academic and research institutes, the food industry, educators and government. Comments on the consultation on the EFSA draft on principles for deriving and applying Dietary Reference Values: The British Nutrition Foundation (BNF) is pleased to have the opportunity to comment on the draft document, discussing the update of European dietary reference values (DRV) for nutrients, as prepared by the EFSA Panel on Dietetic Products, Nutrition and Allergies. BNF has read with great interest the panel's proposals. We think that the panel has generated a valuable document, which will be a good basis for the development of DRVs for nutrients, and we generally agree with the suggestions made in this document. European DRVs are important for European health policy (e.g. setting goals, food fortification policies), for international research (increases comparability of outcomes) and for the food industry (e.g. labelling, food fortification). Using national DRVs, which often vary between European countries, can become confusing in a European context. The most recent DRVs set by the Scientific Committee on Food (SCF) date back to 1993, and therefore BNF strongly agrees that these DRVs need to be updated urgently. Also, we suggest that European DRVs should be reviewed more regularly, to take account of emerging research outcomes and knowledge on nutrient requirements. Yours thankfully, Prof. Judith Buttriss Director General, The British Nutrition Foundation. Dr. Elisabeth Weichselbaum Nutrition Scientist, The British Nutrition Foundation.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Coldiretti - Copa Cogeca	6. Application of dietary reference values for nutrients	Point 6.3 (Reference Values for labelling) 1. As far as DRV can be posted on th label of packaged products, there is some risk to have an hyper-consumption of such food items, against fresh/lose foods that cannot bear indications. In particular, due to reg. 1925/2006, fresh foods cannot show vitamins or minerals content, despite of the fact that are primary dietary sources. On the opposite, processed foods and also integrated foods, can do that. The European Commission, assisted by EFSA, should be able to propose alternative tools of information to consumers, more than simple labelling. Labelling cannot be a viable option for lose foods /fresh foods. 2. Another possible problem is the complexity of labels for the consumers once several nutrition information can be presented. Among those: - DRV; - FBDG; - GDA - Nutrition claims (Annex I ex reg. 1924/2006) - Claims ex art. 13 and 14 (ex reg. 1924/2006) - National schemes (ie, traffic light) - There is a plenty of information which really needs to be coherent. - Furthermore, to really be usable by the consumers, such information should be simple and understandable: which is not always the case when different “metric” are used (ie, GDA and DRV).

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Council for Responsible Nutrition (USA)	1. Introduction	Although comments were not invited (lines 38-40) on the Opinion on the Tolerable Upper Intake Level (UL) that document includes a major omission that should be addressed by EFSA before any policy or regulatory decisions are made on the basis of UL values. Specifically, the method employed by SCF and more recently by EFSA sets no UL for vitamins and minerals for which no adverse effects have been established, i.e., when neither a No Observed Adverse Effect Level (NOAEL) nor a Lowest Observed Adverse Effect Level (LOAEL) can be identified. The absence of a UL is often misinterpreted to mean that risk assessment cannot be applied. This misunderstanding has been corrected in an authoritative report by the Food and Agriculture Organization and World Health Organization. This report provides a definition and criteria for identifying a Highest Observed Intake (HOI) for use where no UL can be established. Basically, the HOI process applies the same criteria as the UL method, except that rather than deriving a UL from a NOAEL or LOAEL the HOI is the highest intake for which the data give sufficient evidence of the absence of adverse effects at that level. Implicit in this method is the recognition that even for vitamins with no established toxicity, such as vitamin B12, the dose-response data have limits. Therefore the HOI would be the highest intake with data that sufficiently exclude adverse effects at that intake. The absence of both the UL and HOI has led to some unjustified and unproductive regulatory policy conclusions. The European Commission and EFSA should revisit its methods publication to address this omission. ---------- 1. Scientific Committee on Food. Opinion on Tolerable Upper Intake Levels for Vitamins and Minerals, 2006 2. A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances, Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment, World Health Organization/Food and Agriculture Organization, 2006 3. Hathcock JN, Shao A. Expanded approach to tolerable upper intake guidelines for nutrients and bioactives substances. J Nutr 2008; 138:1992S-1995S.
Council for Responsible Nutrition (USA)	2. General principles for deriving dietary reference values	Line 174: The term “other substances” was included. This recognizes among the chemical components of food with physiological effectgs, the recognized vitamins and minerals represent only a fraction. Line 257: The word “most” raises a fundamental question of the fraction of the population that should be protected under food policies suggested by the dietary reference values. This issue will be addressed in a more quantitative manner in comments on subsequent sections. While “most” may be a reassuring word, the quantitative recommendation made later is not the only one that would quality as “most.” Does not 51 percent qualify as “most?” Lines 261-2: Is a 2.3 percent (cited as < 2.5%) probability of inadequacy acceptable. If (1) the data are strong and exactly meet the definitions for AR and PRI (i.e., the distribution is normal and the mean and variance are clearly identified, and (2) if every individual in the population consumed (on a long term basis) a diet that provided exactly the PRI amounts of the nutrient in question, the result

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		would be a population in which 2.3 percent of the individuals had "inadequate" nutritional status. Of course, the consequences would depend on the biological effect that had been selected as the basis of the PRI calculation. To examine the acceptability of such as scenario, ask whether a UL value that gave a 2.3 percent probability of adverse effects would be acceptable.
Council for Responsible Nutrition (USA)	3. Terminology and definitions	Lines 293-295: The LTI is described in a way that seems to have conceptual validity as, perhaps, an "anti-PRI," but the word "threshold" is a misnomer. The LTI is not the AR and it is not the intake at which the risk of inadequacy reaches a maximum. More importantly, no advisory or policy recommendations are tied directly to the LTI, perhaps because none are apparent. The LTI has no use and should be removed from this lexicon. Line 306 (Table 1): The arguments against inclusion of the LTI apply here as well, and "Lower Limit of Intake" term described in the Nordic line is misleading. In what way is the LTI a "limit?" The LTI is not the lower limit of possible, recommended, or acceptable intake. The entire discussion and all references to LTI should be deleted.
Council for Responsible Nutrition (USA)	4. Conceptual basis for derivation of dietary reference values	Lines 347-8: The sentence gives appropriate recognition that where a PRI cannot be established, the AI must be used in its stead. The differences in the manner of identification of the PRI and AI have great importance in selecting the basis of labeling values. For AI nutrients, no AR is available to even potentially be selected as the basis of food labels. The AI and PRI are not identical in concept but both are intended to provide adequate for a large majority of the population, in contrast to the AR. These considerations should eliminate the AR from consideration in labeling policy and regulations. The problems with the PRI could be avoided by defining a Tolerable Lower Intake Level (LL) that is directly analogous to the already accepted concepts underlying the UL. The LL concept would extend the risk-based approach being applied at higher intakes to the evaluation of the likely consequences of low intakes. The definition could be exactly analogous to that of the UL. Thus, the LL could be defined as: "the lowest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population." The LL could be identified through application of a method similar to that for the UL, including the same steps: (1) hazard identification, (dose-response evaluation, including selection of a lower NOAEL that avoids accepted indicators of inadequacy), (3) uncertainty assessment and selection of an uncertainty factor (UF), and calculation of an LL = lower NOAEL x UF. The resulting LL would be more similar to the AI than to the PRI in definition, but the datasets that currently identify an AR (and calculation of a PRI) would similarly provide more robust statistical support for the LL. The advantages of the LL include: (1) avoidance of the problem of defining a 2.3 percent risk of inadequacy to be acceptable, (2) symmetry in the U-shaped risk curve common to nutritional risk analysis, allowing greater utility in risk-benefit analysis, and (3) harmony with the nutritional issues risk analysis document by the Codex Committee on Nutrition and Foods for Special Dietary Uses (now at

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		Step 8, reach for the Commission's decision).
Council for Responsible Nutrition (USA)	5. Methods for determining dietary reference values - types of data used	Lines 347-8: The sentence gives appropriate recognition that where a PRI cannot be established, the AI must be used in its stead. The differences in the manner of identification of the PRI and AI have great importance in selecting the basis of labeling values. For AI nutrients, no AR is available to even potentially be selected as the basis of food labels. The AI and PRI are not identical in concept but both are intended to provide adequate for a large majority of the population, in contrast to the AR. These considerations should eliminate the AR from consideration in labeling policy and regulations. The problems with the PRI could be avoided by defining a Tolerable Lower Intake Level (LL) that is directly analogous to the already accepted concepts underlying the UL. The LL concept would extend the risk-based approach being applied at higher intakes to the evaluation of the likely consequences of low intakes. The definition could be exactly analogous to that of the UL. Thus, the LL could be defined as: "the lowest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population." The LL could be identified through application of a method similar to that for the UL, including the same steps: (1) hazard identification, (dose-response evaluation, including selection of a lower NOAEL that avoids accepted indicators of inadequacy), (3) uncertainty assessment and selection of an uncertainty factor (UF), and calculation of an LL = lower NOAEL x UF. The resulting LL would be more similar to the AI than to the PRI in definition, but the datasets that currently identify an AR (and calculation of a PRI) would similarly provide more robust statistical support for the LL. The advantages of the LL include: (1) avoidance of the problem of defining a 2.3 percent risk of inadequacy to be acceptable, (2) symmetry in the U-shaped risk curve common to nutritional risk analysis, allowing greater utility in risk-benefit analysis, and (3) harmony with the nutritional issues risk analysis document by the Codex Committee on Nutrition and Foods for Special Dietary Uses (now at Step 8, reach for the Commission's decision).

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Council for Responsible Nutrition (USA)	Conclusions	SUMMARY: The EFSA draft Principles for Deriving and Applying Dietary Reference Values is generally well written and makes many steps in valid and useful directions. Nonetheless, there are significant areas that need better clarification and improvement to keep pace with progress in the science and policy analysis. The comments from the Council for Responsible (USA) are offered to assist this process. The Summary section of the EFSA draft (Lines 12-97), some statements need to be modified to match changes suggested for the more specific sections in our other comments. Thank you and good progress, John Hathcock
Galenika a.d.	6. Application of dietary reference values for nutrients	The DRV should be established , taking into account that these values should not be used for establishing the values for the dietary supplements neither the upper level of vitamins/minerals in dietary supplements. At this moment I have, as a dietary supp. regulatory affairs manager of the firm where I am eployed, many problems regarding the fact that many people from different Agencies in my country equalize the DRV with the values for the dietry supplements, forgeting that the risk analysis and risk management is the foundation for establishing the vitamin/mineral upper levels in dietry supplements. Kindest regards, Mr.Dusan Obradovic, Pharm M nutr.biochemist Galenika a.d. pharmaceutical factory, Belgrade, 11 080 Batajnicki drum b.b. , Serbia Ditetary Supplements Regulatory Affairs Dept.
Health Council of the Netherlands	1. Introduction	General comment on intake data: The document does not state anything about the value and limitations of intake data. It would be practical to include a section on this and for instance discuss the use of measuring intake on several days and the difference between observed and habitual intake.
Health Council of the Netherlands	2. General principles for deriving dietary reference values	General comment on intake data: The document does not state anything about the value and limitations of intake data. It would be practical to include a section on this and for instance discuss the use of measuring intake on several days and the difference between observed and habitual intake.

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Health Council of the Netherlands	3. Terminology and definitions	General comment on intake data: The document does not state anything about the value and limitations of intake data. It would be practical to include a section on this and for instance discuss the use of measuring intake on several days and the difference between observed and habitual intake.
Health Council of the Netherlands	3. Terminology and definitions	Lines 293-295 and 336-340 Lower threshold intake: What is the use of a lower threshold intake? We doubt that it really adds to the interpretation of intake data. It would be useful if the distribution of individual requirements could be well described, because this information is needed to assess the prevalence of inadequate intakes in a population with the probability approach. However we do not see much practical use of determining the level of intake which is not sufficient for 97,5 percent of the population. In our view metabolic integrity is a mystifying term, which does not belong in a scientific document. We think that the primary focus when setting dietary reference values should be the relationship between intake and (sub)clinical disease. Biochemical abnormality is relevant especially if this can be considered a sign of subclinical disease; i.e. if the relationship between the threshold value for the biochemical parameter and the occurrence or risk of disease is well established.
Health Council of the Netherlands	4. Conceptual basis for derivation of dietary reference values	General comment on intake data: The document does not state anything about the value and limitations of intake data. It would be practical to include a section on this and for instance discuss the use of measuring intake on several days and the difference between observed and habitual intake.
Health Council of the Netherlands	5. Methods for determining dietary reference values - types of data used	General comment on intake data: The document does not state anything about the value and limitations of intake data. It would be practical to include a section on this and for instance discuss the use of measuring intake on several days and the difference between observed and habitual intake.

ORGANISATION	CHAPTER TEXT	COMMENT TEXT
Health Council of the Netherlands	5. Methods for determining dietary reference values - types of data used	Lines 393-509 Judging the evidence: The value of different study designs is discussed. We suggest to add the levels of scientific evidence of different study types and the implication for the weighing of the evidence and the setting of dietary reference intakes. Table 2, lines 510-542 Age categories: Have you considered using the same age categories as Institute of Medicine and Food Standards Australia and New Zealand? It would make comparisons between various dietary reference values (DRV's) easier. In addition, it could facilitate the process of setting DRV's if these values could be critically reviewed as a starting point for setting European DRV's.
Health Council of the Netherlands	6. Application of dietary reference values for nutrients	General comment on intake data: The document does not state anything about the value and limitations of intake data. It would be practical to include a section on this and for instance discuss the use of measuring intake on several days and the difference between observed and habitual intake.
Health Council of the Netherlands	Conclusions	General comment on intake data: The document does not state anything about the value and limitations of intake data. It would be practical to include a section on this and for instance discuss the use of measuring intake on several days and the difference between observed and habitual intake.

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IEURRECA Network of Excellence	1. Introduction	Line 203: DRV comprise both nutrient recommendations and reference intake levels. Do nutrient recommendations and reference intake levels differ and if so, how? Would a nutrient recommendation not be a recommended intake level and therefore a reference intake level? Would a reference intake level not be the intake to aim at, and therefore the recommended nutrient intake or nutrient recommendation? Line 210 (see also comment to line 225): The sentence with physiological needs and metabolic demand seems to suggest that the human body needs different or separate amounts for its physiology and for its metabolism; this may not be what the authors meant to express. Lines 212, 370, 460: Epidemiology is the study of health and the occurrence of diseases and their predictors and causes. Such studies can have an observational or interventional design. In line 212 epidemiological seems to refer to observational (and in line 460 it is explicit); whenever that is the case, latter term is preferable. Line 214: Apart from vitamin D and calcium, fibre is another example for which disease risk was eventually the most important criterion in e.g. the most recent US and Dutch recommendations. Lines 217-219: Systematic genetic differences between the populations of different countries may cause systematic differences in the requirements for certain nutrients. However, current between-country differences in estimated requirements and recommended intakes can typically not be explained by insights in such genetic differences. However, even given a similar physiological requirement, systematic between-country differences in bioavailability (e.g. of iron, as a result of systematic differences in main food sources of iron) or endogenous production (e.g. of vitamin D at different latitude) could give rise to different dietary reference values.
IEURRECA Network of Excellence	2. General principles for deriving dietary reference values	Line 225: See also line 210. Do physiological and metabolic needs differ or, as worded here: do requirement and demand differ as well? Line 230: Gender is listed as a characteristic different from genetic ones, whereas it is one of the genetically determined characteristics. Lines 240-54: Bioavailability is the key phenomenon that explains the dietary or oral nutrient requirement being larger than the physiological requirement; it would be informative to mention that here. Lines 267-9: Here adequate intake levels and recommended intake ranges should be in quotes or in italics, to indicate they are choices of terminology. It seems rather obvious that adequate intakes can be used (as they are adequate) and that recommended intakes should be used (as they are recommended).

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IEURRECA Network of Excellence	3. Terminology and definitions	The Opinion comprises a variety of terms such as dietary (nutrient) recommendations, dietary reference values, dietary requirement (of nutrients), metabolic demand, nutrient recommendations, nutrient requirements, nutrition recommendations, physiological requirements, reference intake levels, and recommendations for nutrient intakes. Clarity could improve by choosing one term to refer to a certain concept and to use that throughout. Reconsider use of concepts developed by United Nations University (UNU, King and Garza, 2007) (lines 281-6). The term Population Reference Intake (PRI) it implies that it can be used for populations only, whereas it can and is used for individuals as well; in both cases, however, with certain limitations (see e.g. Institute of Medicine. Dietary Reference Intakes. National Academies Press, Washington DC, 2006, pp 19-68). PRI is the intake adequate for virtually all people in a population group, as well as the intake that is very likely to be adequate for an individual belonging to the group to which the PRI applies. The PRI's R is frequently interpreted as short for recommended instead of for reference. The UNU term Individual Nutrient Level (INLx) has the opposite drawback of implying it can be used for individuals only, whereas it can be and is used for populations as well (again with limitations for both). The US IOM terminology currently is probably the most widely known and used, and their DRV work has been most extensive. Lines 291, 393, 490: Requirement here seems to refer to dietary requirement, not just physiological or metabolic requirement; see 2.1 and 2.2 (see also comment to lines 240-54). It is preferable to make explicit that from now on that requirement refers to dietary requirement. Lines 26, 293, 632: The use of the Lower Threshold Intake seems very limited, and it may make sense to omit it. On the other hand we realise that if data are available to estimate PRI, LTI can be deducted easily as well. Lines 299, 351-6, 916: Does the R in RI stand for range or for recommended?
IEURRECA Network of Excellence	4. Conceptual basis for derivation of dietary reference values	Line 308: Unlike other similar level heading, this heading is in (small) caps. Lines 310-2: This part is perhaps more easily understandable by spelling out that factors affecting the requirement should reflect in the AR as estimated for a certain group, and the between-person variation in such factors within such group should reflect in the estimate of inter-individual variation of requirement. Subsequently PRI is derived from AR and inter-individual variation. Lines 322, 364: estimated can be left out, because if added before variation it should also be added before AR. All data used are estimated one way or the other anyway. Lines 323-8, 571-3: An (across-individuals) average can be calculated if data points are available for a certain number of individuals, and in that case the inter-individual variation can be calculated over these same data points as well. How can it not be possible to calculate inter-individual variation for a dataset from which an average can be calculated? Line 335: Would the assumption be that for each individual in the group concerned the individual's requirement for all nutrients and energy is met? Line 341: It would be informative to indicate in figure 2 where the level of AI would or could be, i.e. higher than PRI but lower than UL. Lines 345-7: It could be informative to mention that such apparently healthy group could also be e.g. those in the highest quintile of fibre intake in a cohort in which fibre intake was inversely associated with risk of cardiovascular disease (see e.g. IOM´s AI for fibre).

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		Lines 358-60, 579-80, 727: One could reason that for an individual the PRI is for 97.5% likely to exceed that individual's nutrient requirement. Can the unlikely here in unlikely to pose a risk be quantified in a similar way? If above the UL there is an increased prevalence of adverse effects (line 580), then is there also a prevalence under the UL? Or is there one, but is it expectedly zero?
IEURRECA Network of Excellence	5. Methods for determining dietary reference values - types of data used	Ln 374: As 'criterion', it is better to speak of (presence or absence of) deficiency than of risk of deficiency. Ln 380: Delete , after size Ln 381-3: This is about the relation intake/diet and disease risk: delete reduction Ln 383-6, 483 (also 460-74): Clinical endpoints are not just considered the most relevant; by definition they are; that is why they are called endpoints. A surrogate marker in itself is irrelevant; it is relevant only because it marks something else (that is why it is a marker) that is relevant, i.e. an endpoint. Typically observational rather than intervention studies assess the actual endpoints. Ln 45-6, 65-6, 390-2: (…) remains a matter of scientific judgement (…) should be decided on a case-by-case basis. The EURRECA Network of Excellence aims to develop transparent, evidence-based and objective approaches, thus minimising the need for (eminence-based) judgement and case-by-case approaches that limit transparency. Ln 394-5: Feeding studies result in individual estimates of requirement, from which one can calculate both the average and the inter-individual variation, therefore, delete (average). Ln 396-7: Mention that as a result they overestimate requirement. Ln 398-400: Mention that losses would usually be underestimated, retention overestimated, and requirements underestimated. Ln 393-477: From measurements of a status marker at different levels of intake in an individual one can estimate that individual's requirement as the minimal intake needed to reach, in that individual, the optimal level of that marker. From such data for a number of individuals we can calculate the average requirement and its inter-individual variation. In many cases, however, we only have single measurements of both intake and marker in a group of individuals. Plotting marker level against intake across such individuals can reveal the average requirement in the group under study; estimation of inter-individual variation in requirement seems less straightforward and less accurate, though not impossible. Ln 435: of the first can be left out. Ln 437: Insert . after nutrients Ln 441-2: Human milk does not necessarily have in all respects the perfect composition for the infant, as its composition may to some extent be a compromise between the mother's and the infant's health. If the mother would e.g. give away too much of her calcium stores during lactation, she would endanger her own health and consequently that of her baby as well. Ln 446-8: Important to refer to (apparently) healthy infants. Ln 460-74 (see also ad 383-6): Crucial paragraphs. Evidence from observational studies indeed adds less to the plausibility of causality than an otherwise similar study with an interventional design. However, intervention studies often provide evidence for effects on markers of which the actual relevance for health and disease is not known or uncertain. So intervention studies tend to provide stronger

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		evidence for effects on phenomena of unknown or uncertain relevance for human health, whereas observational studies tend to provide less strong evidence for effects on health and disease itself. Ln 475-477 (see also ad 383-6): Here transforming scientific judgements into objective evidence-based approaches seems to emerge. EURRECA aims to produce transparent and standardised approaches for assessing consistency, strength and quality of studies and weighing the available evidence obtained. Consequently, EFSA expectedly can benefit from EURRECA. Ln 491: Over time requirement may also vary within individuals. Ln 510-42, 538-42: With overweight, actual weight data overestimate nutrient and energy needs. Micronutrient requirements depending on body weight often means depending on lean body mass rather than on the metabolically – but not endocrinologically - less active adipose tissue. At the same time, people with overweight generally have not only more adipose tissue but also some more lean body mass.
IEURRECA Network of Excellence	6. Application of dietary reference values for nutrients	Ln 74-6: Rather than the fraction of a population under AR, the preferred approach is a probabilistic one. Ln 550: Use of balance as a metaphor in nutrition has a long tradition. In nutrition the principle of a balance would be that if one consumes more of x one must, in order to maintain balance, consume more of y as well. In nutrition this phenomenon exists, e.g. for certain vitamins in relation to protein or energy intake. A perhaps related mechanism is that the intake of energy and nutrients that must balance their use or losses; some would refer to this as balance, others as equalisation or compensation. For the rest balance and balanced diet seem neither applicable nor useful in nutrition. Most important for many of us is that intakes of energy and of certain nutrients are too high (e.g. saturated fats, salt, alcohol) or too low (e.g. fibre, folate/folic acid), which cannot be balanced by de- or increasing the intakes of other nutrients. What is important, however, is interaction between the actions of nutrients and their requirements; that is another phenomenon. Ln 558-60: Such methods can to some extent only remove the effect of day-to-day variation. Ln 578-9: The usually does not apply here; it is by definition that an intake higher than an individual's requirement does not convey additional health benefit; if it would, then requirement has been underestimated. Similarly at population level: an intake higher than the PRI would give additional health benefit in no more than 2.5 % of the population; if it would do so for more than 2.5 %, then the PRI is too low. Ln 582-4: Here average does not apply, unless average individual daily intakes are meant here. Ln 585-6: More concise by leaving out use of, lead to an and of Ln 590: . missing after mean Ln 595-6: More concise by leaving out application of and shorten result in an overestimation of to overestimate Ln 603, 709-10: If all members of a population to which a certain PRI applies consume exactly the PRI, then in expectedly 97.5 % of that population the intake will exceed requirement whereas for 2.5 % of the population intake will not meet the requirement.

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		Ln 608-9: This does not depend on AI and average intake only, but also largely on the inter-individual distributions of both intake and actual individual requirements. Ln 610 (see also 771-2): RIs for macronutrients apply to individuals, and groups comprise (are series of) individuals, so RIs necessarily apply to groups as well. Ln 622-7, 771-2 (also 610, 691-5, 774-5): Suggests that for groups dietary intake data alone can ascertain nutritional status. If dietary intake data alone cannot ascertain an individual's nutritional status, then how can such data ascertain nutritional status of a number of individuals (i.e. a group)? Related to: DRVs can be used in both planning and monitoring of diets in both groups and individuals. Ln 633-5 (see also 651-3): It is clear that an individual below AR has a probability of 50 % requirement not being met. Is the point being made here that this 50 % is very likely? Ln 641: is should read are Ln 645: Would recent entail a period of weeks, months or years? Ln 651-3 (also 633-5): Here inadequate refers to intakes below AR; if just below AR they still meet the requirements of almost 50 % of a population. Ln 677: Using PRI for dietary planning indeed entails overestimation for 47.5 % of individuals; using EAR would result in insufficient intake for 50 %. Ln 691-5 (also 610, 771-5): Excellent relevant papers to add to reference list: Murphy SP, Barr SI, Yates AA. The Recommended Dietary Allowance (RDA) should not be abandoned: an individual is both an individual and a member of a group. Nutr Rev 2006;64:313-8 Beaton GH. When is an individual an individual versus a member of a group? An issue in the application of the dietary reference intakes. Nutr Rev 2006;64:211-25
IEURRECA Network of Excellence	Conclusions	Lines 763-5: It depends how one uses PRI for this purpose; the sentence mainly applies to the situation that a considerable part of a population has an intake lower than the PRI. If most individuals in a group have an intake around PRI or higher, then one can conclude that almost all have an adequate intake. Lines 772: Perhaps more informative to specify likely inadequate by saying that at AR the likelihood of inadequacy is 50 %, and that that likelihood is higher when intake is lower than AR. Lines 774-5 (see also 610, 691-5, 771-2): Exactly the same applies to groups. Line 785: PASSCLAIM is very relevant as it provided carefully constructed criteria for the substantiation of health effects, be it for use in health claims on foods or in understanding nutrient requirements. Aggett PJ et al. PASSCLAIM: consensus on criteria. Eur J Nutr 2005;44 Suppl 1:5-30
Institut Catalá Salut	6. Application of dietary reference values for nutrients	3.- Terminoly and definitions 6.- Application of dietary ... conclusions

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KTL	1. Introduction	The opinion is not suggesting any changes in text. Line 158. Our main concern is in carbohydrate fractions, covering available carbohydrate, sugars and fibre. The opinion is presenting the principles to derive Dietary Reference values. However, we want to emphasize that there is a need to give a profound description of carbohydrates and fibre in the context of food. No dietary recommendation enhances the carbohydrate intake per se but intake of complex carbohydrate excluding the intake of refined carbohydrates and sugar to the minimum. In dietary guidelines the natural combination of starch and fibre is considered the best selection. The carbohydrate quality is partly dependent on fibre content but it is necessary to have these two separate concepts. We consider this aspect as the most essential one for food-based dietary guidelines and this statement should be mentioned in the principles for deriving and applying Dietary Reference Values (lines 188, 273). Line 223, please add the reference WHO 2003. Line 309. It could be reader-friendly to have the total text Population Reference Intake after the agronym PRI. Line 331. See the previous comment Line 336. See the previous comment.

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Martek Biosciences	1. Introduction	Summary Section In lines 71-73 of the Principles document, EFSA reminds readers that DRVs are important for establishing reference values in food labeling. A single DRV for all omega-3 fatty acids will not provide sufficient information to allow consumers to make meaningful decisions about products they purchase and consume. While recommendations for gram levels of ALA may be appropriate, recommendations for the long chain n-3s may be in milligrams due to their higher potency. Consumers can only make appropriate comparisons and decisions regarding foods if complete n-3 information and guidance is available. For many fatty acids (particularly saturated- and trans- fatty acids), the purpose of a DRV is to limit or even discourage consumption. The case of the omega-3 fatty acids is different in this respect. In the case of the n-3 fatty acids, including ALA, DHA, and EPA, the purpose of the recommendation is to encourage their consumption. Technically these fatty acids provide calories, however this is where the relationship with 'macro nutrients' ends. The long chain n-3 fatty acids are included in small quantities in the diet in order to provide beneficial effects on health, a characteristic that is more similar to micronutrient description. Each of the fatty acids provides unique benefits and potency. Lumping together of the individual omega-3 fatty acids would be misleading to consumers, as would the lumping together of all polyunsaturated fats. Independent DRVs for ALA, DHA, and EPA will help clarify this issue for consumers. Summary In light of the above, we believe it is important for EFSA to utilize a broad range of outcome measures when establishing DRVs and to recognize the unique needs of various age and gender groups. Nutrition research has progressed beyond the classic models of deficiency to recognize the beneficial effects of nutrients. The example provided by the omega-3 fatty acids shows the importance of establishing DRVs for additional nutrients which provide such benefits. In light of the current literature, the establishment of a single DRV for all omega-3 fatty acids is misleading and will not provide consumers with the information they seek. Rather, the only way to ensure that consumers have access to meaningful information about omega-3 fatty acid content is to establish separate DRVs for DHA, EPA and ALA and to allow individual identification of these nutrients on food labels.

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National Food Institute, Technical University of Denmark	2. General principles for deriving dietary reference values	General remarks The draft appears as a thorough description of the principles for the existing dietary reference values (DRV"s) as well as proposals for the forthcoming European DRV"s. The term the Lower Threshold Intake (LTI) is difficult to apply. It differs considerably from the Lower Limit Intake (LI) in e.g. the Nordic Nutrition recommendations (NNR), and LTI is not used either in the assessment of the adequacy of nutrient intake in populations or in individuals. We suggest that LTI is left out or, alternatively, is defined in agreement with NNR and used as proposed in NNR. The Panel has understandably decided not to address the Tolerable Upper intake Level (UL) as this has been assessed previously. Anyway, it would be useful if the use of UL was further explained in a small separate chapter and the UL"s were listed in a table. On behalf of the Department of Nutrition, National Food Institute, Technical University of Denmark. Agnes N. Pedersen Senior Scientist, M.D., Ph.D.
UNESDA - Union of European Beverages Associations	1. Introduction	Page 5 (Line 171) EFSA is asked by the EC to "… provide advice on energy, macronutrients and dietary fibre. Specifically advice is requested on the following dietary components: Carbohydrates, including sugars; Fats, including saturated fatty acids, poly-unsaturated fatty acids and monounsaturated fatty acids, trans fatty acids; Protein and Dietary fibre. In addition, EFSA is asked to advise on population reference intakes of micronutrients in the diet and, if considered appropriate, other essential substances with a nutritional or physiological effect in the context of a balanced diet which, when part of an overall healthy lifestyle, contribute to good health through optimal nutrition". Water, however, is not mentioned. As EFSA acknowledges that water and adequate hydration of the body is essential for health and life - and even has drafted an opinion on Dietary reference values for water - then water should appear as a dietary component in page 6 of the Opinion.